

**RECEIVED**

JUL 19 2004

TECHNOLOGY CENTER 3700

PTO/SB/08A (03-00)

Approved for use through 10/31/2002. 0318 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

**SUPPLEMENTAL INFORMATION  
DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	09/776,125
Filing Date	February 2, 2001
First Named Inventor	Seth A. Foerster et al.
Group Art Unit	3731
Examiner Name	Jessica Baxter
Attorney Docket Number	END -723

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Kind Code	Number (if known)			
JLB		Re.	35,391	Brauman	12-03-1996	ALL
			3,194,239	Sullivan	01-16-1963	ALL
			4,298,998	Naficy	11-10-1981	ALL
			4,347,234	Wahlig et al.	08-31-1982	ALL
			4,365,572	Gallemin et al. <i>Sturgeson, IV</i>	11-02-1982	ALL
			4,511,653	Play et al.	04-16-1985	ALL
			4,703,108	Silver et al.	10/27/1987	ALL
			5,061,281	Mares et al.	10-29-1991	ALL
			5,085,629	Golberg et al.	02-04-1992	ALL
			5,120,802	Mares et al.	06-09-1992	ALL
			5,127,916	Spencer et al.	07-07-1992	ALL
			5,192,300	Fowler	03-19-1993	ALL
			5,195,988	Haaga	03-23-1993	ALL
			5,274,074	Tang et al.	12-28-1993	ALL
			5,433,751	Christel et al.	07-18-1995	ALL
			5,470,308	Edwards et al.	11-28-1995	ALL
			5,514,379	Weissleder et al.	05-07-1996	ALL
			5,522,896	Prescott	06-04-1996	ALL
			5,824,081	Knapp et al.	10-20-1998	ALL
			5,869,080	McGregor et al.	02-09-1999	ALL
			5,922,024	Jamzen et al.	07-13-1999	ALL
			6,066,325	Wallace et al.	05-23-2000	ALL
			6,214,045	BI Corbitt, Jr. et al.	04-10-2001	ALL
			2004/0024304	A1 Foerster et al.	02-05-2004	ALL
JLB			2001/0034528	A1 Foerster et al.	10-25-2001	ALL
Examiner Signature	<i>Jessica E. Baxter</i>				Date Considered	12/20/04



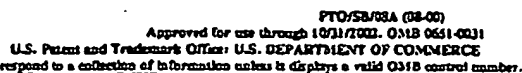
RECEIVED  
JUL 19 2004  
TECHNOLOGY CENTER 3700

PTO/SB/03A (03-00)

Approved for use through 10/31/2002. ONIB 0631-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1448A/PTO		Application Number	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		09/776,125	
Sheet 2 of 3		Filing Date	
		February 2, 2001	
		First Named Inventor	
		Seth A. Foerster et al.	
		Group Art Unit	
		3731	
		Examiner Name	
		Jessica Baxter	
		Attorney Docket Number	
		END -723	
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials	Cite No.	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
JLB		WANG HOM-LAY et al. "Evaluation of an Absorbable Collagen Membrane in Treating Class II Furcation Defects", pp 1029-1036. November 1994.	
		BROPHY M. REGINA et al. "Biodegradable Polyester Polymers as Drug Carriers". Pp 1-25.	
		SWARBRICK JAMES and BOYLAN JAMES. "Bioabsorbable Polymers." The Encyclopedia of Pharmaceutical Technology. Vol. 1. Absorption of Drugs to Bioavailability of Drugs and Bioequivalence. New York and Basel. Pp 465-476.	
		PARK, KINAM; SHALABY, WALEED AND PARK HAESUN. "Biodegradable Hydrogels for Drug Delivery." Purdue University School of Pharmacy. Pp. 13-19.	
		TSCHAKALOFF A. et al. "Degradation Kinetics of Biodegradable implants depending on the site of Implantation." Int. Journal of Oral & Maxillofacial Surgery. 1994. Pp. 443-445.	
		VERT, MICHEL, MAUDUIT, JACQUES AND LI, SUMING. "Biodegradation of PLGA Polymers Increasing complexity." Biomaterials 1994 Vol. 15. No. 15. Pp. 1209-1213.	
		HOFFMAN, G.O. "Biodegradable Implants in Traumatology A Review on the State-of-the Art." Arch Orthop Trauma Surgery. 1995 Pp. 114: 123-132.	
		BOSTMAN, O. AND PIHLAJAMAKI, H. "Clinical Biocompatibility of Biodegradable Orthopaedic Implants for Internal Fixation." Biomaterials 21 (2000) Pp. 2615-2621.	
		ALONSO, MARIA J., GUPTA, RAJESH K. et al. "Biodegradable Microspheres as Controlled-Release Tetanus Toxoid Delivery Systems." Vaccine 1994 Vol. 12 No. 4. Pp. 299-304.	
		AN, YUEHUEI H., WOOLF, SHANE K., FRIEDMAN, RICHARD. "Pre-clinical in Vivo Evaluation of Orthopaedic Bioabsorbable Devices." Biomaterials 21 (2000) Pp. 2635-2652.	
		MOONEY, D.J. et al. "Transplantation of Hepatocytes Using Porous, Biodegradable Sponges." Transplantation Proceedings, Vol. 26, No. 6 Dec. 1994 Pp 3425-3426.	
		CUTRIGHT, DUANE E. et al. "Degradation Rates of Polymers and Copolymers of Polylactic and Polyglycolic Acids." U.S. Army Institute of Dental Research, Walter Reed Army Medical Center, Washington, D. C. Pp. 142-151	
		KULKARNI, R. K. PHD. Et al.; "Polylactic Acid for Surgical Implants." Arch Surgery. Vol. 93, Nov. 1866 Pp. 839-843.	
		KULKARNI, R. K. PHD. Et al.; "Biodegradable Poly(lactic acid) Polymers." U.S. Army Institute of Dental Research, Walter Reed Army Medical Center, Washington, D. C. (1971) Vol. 5, Pp. 169-181	
		CHASIN, MARK AND LANGER, ROBERT. - LEWIS, DANNY H. "Biodegradable Polymers as Drug Delivery Systems." Controlled Release of Bioactive Agents from Lactide/Glycolide Polymers Ch. 1 Pp -41 (1990). And BOGDANSKY, SIMON "Natural Polymers as Drug Delivery Systems." Pp. 231-259.	
		HUANG, SAMUEL J. et al.; "Hydrophilic-Hydrophobic Biodegradable Polymers: Release characteristics of Hydrogen-Bonded, Ring-Containing Polymer Matrices. (1994) Biomaterials (1994, Vol. 15 No. 15 Pp. 1243-1247.	
		BECKER, PAUL L. "Comparison of Antibiotic Release from Polymethylmethacrylate Beads and Sponge Collagen." Journal of Orthopaedic Research. (1994) Vol. 12, No. 5.	
		MACKINNON, SUSAN E. "Clinical Nerve Reconstruction with a Bioabsorbable Polyglycolic Acid Tube." Plastic and Reconstructive Surgery, March 1990.	
		NAKAMURA, T., et al. "New Bioabsorbable Pledgets and Non-Woven Fabrics Made from Polyglycolide (PGA) for Pulmonary Surgery: Clinical Experience." Thoracic Cardiovascular Surgeons. (1990) Pp. 81-85.	
		TONG, XIAO-JIE, et al.; "Sciatic Nerve Regeneration Navigated by Laminin-Fibronectin Double Coated Biodegradable Collagen Grafts in Rats." BRAIN RESEARCH 663 (1994) Pp. 155-162.	
		MATSUSUE, YOSHITAKA, et al.; "In Vitro and In Vivo Studies on Bioabsorbable Ultra-High-Strength Poly (L-Lactide) Rods." Journal of Biomedical Materials Research (1992) Vol. 26, Pp. 1553-1567.	
		HUTMACHER, DIETMAR. "A Review of Material Properties of Biodegradable and Bioresorbable Polymers and Devices for GTR and GBR Applications." The International Journal of Oral & Maxillofacial Implants." (1996) Vol. 11 No 5. Pp. 667-678.	
ME			
Examiner Signature	Date Considered		
Jessica P. Baxter	12/20/04		



**SUPPLEMENTAL INFORMATION  
DISCLOSURE  
STATEMENT BY APPLICANT**

Sheet 3 of 3

<b>Application Number</b>	<b>09/776,125</b>
<b>Filing Date</b>	<b>February 2, 2001</b>
<b>First Named Inventor</b>	<b>Seth A. Foerster et al.</b>
<b>Group Art Unit</b>	<b>3731</b>
<b>Examiner Name</b>	<b>Jessica Baxter</b>
<b>Attorney Docket Number</b>	<b>END -723</b>

[illegible]

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A-PTO

MAR 25 2005

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet	1	of	2	Application No.	09/776,125
				Filing Date	February 2, 2001
				First Named Inventor	Foerster
				Art Unit	3731
				Examiner Name	Baxter
				Attorney Docket No.	032,290-108 (formerly END-723)

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document No. Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
JMS	1.	us-4,103,690	08/1978	Harris	
	2.	us-5,002,548	03/1991	Campbell, et al.	
	3.	us-5,024,727	06/1991	Campbell, et al.	
	4.	us-5,112,299	05/1992	Pascaloff	
	5.	us-5,133,661	07/1992	Euvrard	
	6.	us-5,158,565	10/1992	Marcadis, et al.	
	7.	us-5,192,292	03/1993	Cezana, et al.	
	8.	us-5,395,319	03/1995	Hirsch, et al.	
	9.	us-5,445,167	08/1995	Yoon, et al.	
	10.	us-5,469,854	11/1995	Unger, et al.	
	11.	us-5,496,314	03/1996	Eggers	
	12.	us-5,681,262	10/1997	Isse	
	13.	us-5,902,310	05/1999	Foerster, et al.	
	14.	us-6,053,925	04/2000	Barnhart	
	15.	us-5,645,566	07/1997	Brenneman	
	16.	us-5,670,161	09/1997	Brenneman	
	17.	us-4,230,123	04/1997	Hawkins	
	18.	us-6,347,241	02/2002	Burbank	
	19.	us-6,371,904	04/2002	Sirimanne	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
JMS	20.	GB 2,132,091	07/1984	Norton, et al.		
	21.	WO 98/47430	10/1998	Vascular Science Inc.		
	22.	FR 2714284	06/1995	Leriche		
	23.	WO 96/08208	03/1996	Biopsys		

Examiner  
Signature

James E. Baxter

Date  
Considered

6/9/05

\*Examiner: Initial reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A-PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	2	Attorney Docket No.	032,290-108 (formerly END-723)
-------	---	----	---	---------------------	--------------------------------

## Complete if Known

Application No.	09/776,125
Filing Date	February 2, 2001
First Named Inventor	Foerster
Art Unit	3731
Examiner Name	Baxter

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup> Kind Code (if known)				
JMB	24.	DE	4403789	08/1995	Schering AG		
	25.	DE	4330958	03/1995	Schering AG		
	26.	EP	0769281	04/1997	U.S. Surgical Corp.		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
JMB	27.	S.S. KRAMER, et al., "A Permanent Radiopaque Marker Technique for the Study of Pharyngeal Swallowing in Dogs", <i>Dysphagia</i> (1987) pp. 163-167	
	28.	HOMER, et al., "The Geographic Cluster of Microcalcifications of the Breast", <i>Surgery, Gynecology &amp; Obstetrics</i> (1985)	
	29.	FINAN, et al., "Interstitial Radiotherapy for Early Stage Vaginal Cancer", <i>The Journal of Reproductive Medicine</i> (1993) Vol. 38, No. 3	
JMB	30.	DUFRANE, P. et al., "Prebiopsy Localization of Non-Palpable Breast Cancer", <i>Journal Belgede Radiologie</i> (October 1, 1990) Vol. 73, No. 5	

Examiner  
Signature

Jordan R. Baxter

Date  
Considered

6/9/05

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.